



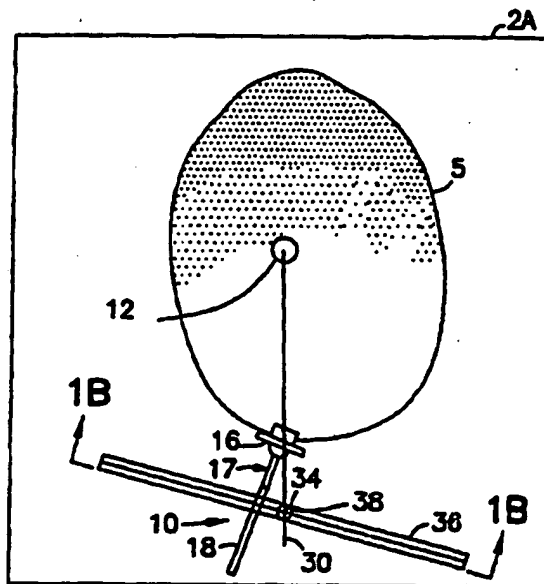
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61B 19/00		A1	(11) International Publication Number: WO 00/19927
			(43) International Publication Date: 13 April 2000 (13.04.00)
(21) International Application Number: PCT/US99/23673		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
(22) International Filing Date: 8 October 1999 (08.10.99)			
(30) Priority Data: 09/168,792 8 October 1998 (08.10.98) US 09/238,749 28 January 1999 (28.01.99) US			
(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application US 09/238,749 (CON) Filed on 28 January 1999 (28.01.99)			
(71) Applicant (for all designated States except US): REGENTS OF THE UNIVERSITY OF MINNESOTA [US/US]; Morrill Hall, 100 Church Street S.E., Minneapolis, MN 55455 (US).		Published With international search report.	
(72) Inventors; and			
(75) Inventors/Applicants (for US only): TRUWIT, Charles, L. [US/US]; 378 Ferndale Road West, Wayzata, MN 55391 (US). LIU, Haiying [CN/US]; Suite A, 1021 29th Avenue S.E., Minneapolis, MN 55414 (US).			
(74) Agent: VIKSNINS, Ann, S.; Schwegman, Lundberg, Woessner & Kluth, P.O. Box 2938, Minneapolis, MN 55402 (US).			

(54) Title: METHOD AND APPARATUS FOR POSITIONING A DEVICE IN A BODY

(57) Abstract

There is disclosed a method of positioning an interventional device in a body using a guide (17) pivoting about a pivot point, comprising locating the spatial coordinates of a target (12) and the pivot point, determining a third point (34) outside of the body lying along or proximate a line (30) extending through the target and pivot point, and aligning the axis of the guide with the third point (34) using an imaging system. There is also disclosed a medical imaging system including a processing unit and computer software operative on the processing unit to permit an operator of the system to locate the spatial coordinates of a target point (12) and a pivot point of a guide (17), and determine a third point (34) outside of the body lying along or proximate a line (30) extending through the target and pivot point. This medical imaging system may further include computer software operative on the processing unit to assist an operator in obtaining an image by which the axis of the guide can be aligned with the third point (34) using an imaging system. There is also disclosed an article of manufacture comprising a computer program encoded in a carrier, wherein the program is operative on a processing unit of a medical imaging system to permit an operator of the system to locate the spatial coordinates of a target point (12) and a pivot point of a guide (17), and determine a third point (34) outside of the body lying along or proximate a line (30) extending through the target (12) and pivot point.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	JP	Japan	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	KE	Kenya	NL	Netherlands	VN	Viet Nam
CG	Congo	KG	Kyrgyzstan	NO	Norway	YU	Yugoslavia
CH	Switzerland	KP	Democratic People's Republic of Korea	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KR	Republic of Korea	PL	Poland		
CM	Cameroon	KZ	Kazakstan	PT	Portugal		
CN	China	LC	Saint Lucia	RO	Romania		
CU	Cuba	LI	Liechtenstein	RU	Russian Federation		
CZ	Czech Republic	LK	Sri Lanka	SD	Sudan		
DE	Germany	LR	Liberia	SE	Sweden		
DK	Denmark			SG	Singapore		
EE	Estonia						

METHOD AND APPARATUS FOR POSITIONING A DEVICE IN A BODY

This application is a continuation-in-part of U.S. Application Serial No. 09/168,792 filed October 8, 1998. USSN 09/168,792 is incorporated by reference herein.

Technical Field of the Invention

5 The present invention pertains generally to the field of medicine, and more particularly to positioning an interventional device in a body using a medical imaging system.

Background of the Invention

10 Computed tomography (CT)-guided biopsies have been performed since the early days of CT scanning when it became apparent that the cross sectional imaging modality offered unprecedented abilities to visualize the needle in cross section to verify positioning within a lesion. Over the last 15 years, the methodology for the CT-guided biopsy has remained largely one of trial and error. Essentially, a scan of the appropriate body part is made and a mental
15 calculation of the trajectory is made following a depth calculation on the computer console. The depth is then transferred to the interventional device which has been marked. The interventional device is then inserted, removed, and reinserted repeatedly with repeat scanning at the appropriate interventional device position to confirm proper placement or improper placement. Obviously,
20 this technique of trial and error introduces undesirable delays, risks, costs and, in some cases, exposure to unwanted radiation.

 In addition to the matter of CT-guided biopsies, there has been much recent work in the field of MR-guided surgery, including biopsies and other minimally-invasive procedures. At present, methods of trajectory localization
25 under MR are based largely on frameless stereotactic concepts. While this is a feasible methodology for many situations, there remains an issue of cost. To date, there has not been a method proposed that is simple, accurate, and inexpensive for use in the MR setting.

 Therefore, there remains a need for a method for locating a interventional
30 device in a body part which is faster and more convenient.

Summary of the Invention

According to one example embodiment, the present invention provides a method of positioning an interventional device in a body using a guide pivoting about a pivot point, comprising locating the spatial coordinates (or the image display of a point corresponding to said coordinates, even if said coordinates are not explicitly stated because a computer is capable of interpreting the mathematical relationship of the display to the true coordinates) of a target and the pivot point, determining a third point outside of the body lying along or proximate a line extending through the target and pivot point, and aligning the axis of the guide with the third point using an imaging system.

According to another example embodiment, the invention provides a medical imaging system including a processing unit and computer software operative on the processing unit to permit an operator of the system to locate the spatial coordinates of a target point and a pivot point of a guide, and determine a third point outside of the body lying along or proximate a line extending through the target and pivot point. This medical imaging system may further include computer software operative on the processing unit to assist an operator in obtaining an image by which the axis of the guide can be aligned with the third point using an imaging system.

According to another embodiment, the invention provides a method of using the MR signal from one or more radio frequency microcoils placed on the trajectory alignment stem at the pivot point and at the at least third point to determine the spatial locations of these two coils, and hence the position of the alignment stem, including its orientation. Moreover, with this information determined and therefore known to the MR scanner computer, the trajectory alignment stem could be realigned to match the desired trajectory, either manually, by remote or robotic control, or by control of the MR scanner computer itself, by means of an interface with a servo mechanism either directly or indirectly attached or related to the trajectory alignment stem.

According to another embodiment, the invention provides an article of manufacture comprising a computer program encoded in a carrier, wherein the program is operative on a processing unit of a medical imaging system to permit an operator of the system to locate the spatial coordinates of a target point and a

pivot point of a guide, and determine a third point outside of the body lying along or proximate a line extending through the target and pivot point.

According to yet another embodiment, the invention may provide that the axis of the guide is aligned automatically under software control.

5 Brief Description of the Drawing

Figures 1A, 1B and 1C are MRI images illustrating one example method of the invention, with the image of Figure 1B taken along the lines 1B-1B of Figure 1A.

Figures 2A and 2B illustrate post-alignment imaging views.

10 Figure 3 is a flow diagram of an example method of the present invention.

Figures 4 illustrates a medical imaging system and software components according to an example embodiment of the invention.

Figure 5 illustrates an example trajectory guide.

15 Figures 6 and 7 illustrate alternate embodiments of the invention.

Detailed Description of the Invention

In the following detailed description of the preferred embodiments, reference is made to the accompanying drawings that form a part hereof, and in which are shown by way of illustration specific embodiments in which the
20 invention may be practiced. It is understood that other embodiments may be utilized and structural changes may be made without departing from the scope of the present invention.

The present invention, as described below, provides method and apparatus for aligning an straight (or substantially straight), elongate, point
25 pivoted interventional device to an orientation in a human or animal body. As used herein, the term "interventional device" refers to any medical instrument, such as a biopsy needle, probe or other type of needle (etc...). The invention is described below in an example embodiment wherein it is applied to position an interventional device in a human brain. It shall be understood, however, that the
30 invention is in no way limited to use in positioning interventional devices in the brain, but can applied broadly to the positioning of interventional devices in any part of human or animal bodies.

Example Method Using Magnetic Resonance Imaging

The example embodiment set forth below provides a method of MRI-guided biopsy involving an intracranial lesion along a trajectory oriented somewhat parallel to the long axis of the patient, as might be used for a biopsy of a high frontal lobe lesion. The long axis of the patient is the axis that is generally coaxial to the length of the patient's body. This method is described with reference to Figures 1A, 1B and 1C, which illustrate MRI images 2A, 2B and 2C, respectively. Either prior to, or, in one example embodiment, following, administration of an intravenous contrast agent to the patient, a limited MRI scan is obtained through the head 5, particularly involving the region of the planned target 12. The benefit of first administering intravenous contrast is two fold. First, there is quite often contrast enhancement of the targeted lesion itself, making it easier to identify the lesion, and second, there is often contrast enhancement of the cortical veins overlying the region of the planned trajectory. Since these are structures that are to be avoided if possible so as to minimize potential bleeding, it is helpful to identify these veins prior to the determination of the trajectory.

Once the target 12 is identified, the trajectory is determined using the scanner. A point on the scalp is chosen for an entry point, thereby creating a surgical approach. The approach can be verified either by performing a multiplanar reconstruction of the already obtained imaging data, or by simply performing a new single slice image along the desired trajectory. If the latter method is used, the scan plane can be easily adjusted, if necessary, until it is determined that the surgical approach is along the axis of the current scan plan. Alternatively, the entry point is determined by other means.

Once the entry point is determined, a trajectory guide 10 is surgically implanted either on the surface of the calvarium or in a burr hole that is drilled at this point. The design of trajectory guide 10 is not important to the invention, other than it includes, as illustrated in the example guide 10 of Figure 5, a guide member 17 that pivots about a pivot point. As illustrated in Figure 5, guide member 17 includes a lower portion 17A which is pivotally connected to a base 16, and an upper portion 17B that can receive an interventional device, or a guide stem 18 that is used during the alignment process. Further information on

the example trajectory guide 10 illustrated in Figure 5, and information on other possible guides that may be used with the present invention, can be found in U.S. Patent Application Serial No. 09/078913, entitled "Remote Actuation of Trajectory Guide", filed May 14, 1998. It is noted that while the pivot point of example guide 10 is located proximate the surface of the body, the pivot point may be above the surface of the body, for example where it is suspended above or outside the body with an articulated arm.

Once the trajectory guide 10 and alignment stem 18 are in place and the trajectory is in line with scanning plane, (which in Figure 1A provides an image slice taken along a plane encompassing the target 12 and at least the base 16 of the of the trajectory guide 10), several spatial location points in the 3D space of the MRI scan are located: one in the head, one near or above the surface of the head, and one outside. First, the x, y, z coordinates of the target 12 are determined by the operator from the images obtained in the initial MRI scan of the head. Second, the x, y, z coordinates of the pivot point of the guide member 17 are also determined by the operator from the MRI scan image(s).

Once these two points are known, there is determined mathematically a line 30 which extends from the target 12, through the pivot point of the guide member 17 and out into the space 32 outside the head 5. This line, which can be displayed on the scan plane (which is aligned with the surgical approach) of the current or reconstructed image, represents the trajectory required to reach the desired target with an interventional device. According to one example embodiment of the invention, the line 30 is drawn to extend away from the base 16 about two thirds of the distance from the base 16 up to the free end of the stem 18. A point 34 is then chosen along line 30. Point 34 should fall along a 3-D circumferential arc described by the alignment stem 18 of the trajectory guide which, according to one example embodiment, contains a MRI-visible marker 19, positioned at the same approximate distance from the base 16 as the distance of point 34 from the base 16, to make it clearly visible in a new image along the plane of the current or reconstructed image. Stem 18 may be made entirely of a MRI-visible marker material, or the marker 19 may be limited to a segment of the stem 18. Point 34 may be chosen by the operator on the line 30 when drawn

on the scanner display, or it may be determined mathematically without operator intervention.

It is worth noting that while the description herein is based on mathematical precepts, in reality, most modern CT and MR scanners, and other imaging equipment, no longer need the operator to manually type in coordinates, as described above. Most scanner consoles work like home computers with a mouse, in that a cursor can be dropped on the screen to denote a point, a line can be drawn on the operator console from one point to another, even without the operator knowing the true coordinates of the points used to determine the line. Nevertheless, behind the screen façade, the computer is in fact translating the very points displayed into spatial coordinates and following mathematical models. Thus, in practice, most operators of the methods presented herein will not in fact be required to perform the proposed steps, but merely will need to point and click with a computer mouse or similar device to create the geometric plan of trajectory described herein.

In addition to the simple method described above and as described further below, it is possible to envision that the alignment of the trajectory alignment stem could be carried out by other visualization methods, such as with laser, infrared, or light of other frequencies or other energy sources focused at a point in space determined by the operator to be the location of point 34 described above. Moreover, it is easy to envision that the method of recognition by the operator of closer alignment of the trajectory alignment stem to line 30 need not even be visual, but could be audible, such that, for example, the repeat rate of a repeating beep might vary depending on the success or failure of various movements to align the stem (i.e. a slower rate of beeping, if moving the stem further away from line 30, a faster rate of beeping, if approximating line 30, and a continuous sound when the alignment is deemed successful.

Using the x, y, z coordinates of point 34, as either calculated automatically or obtained from the point selected by the operator on line 30, a scanning plane 36 is chosen to include point 34 even though the target itself is not visualized within the plane. The point 34 is then marked (38) on the trajectory guide alignment plane. Two dimensional (2D) sequential scans are then obtained along plane 36 (Figure 1B) with interactive positioning of the

trajectory guide alignment stem 18 until such time as the MRI-visible marker 19 on the alignment stem 18 comes into view and is positioned at the desired x, y, z coordinates. As illustrated in Figure 1B, the stem 18 is proximate the mark 38, such that stem 18 can be easily moved into place in alignment with mark 38 with reference to a single point in space, which, from the perspective of Figure 1B, requires alignment only with respect to "x" and "y" coordinates lying in the trajectory guide alignment plane. Once the stem 18 aligns with points "x" and "y", it is known to be coaxially aligned with line 30. The alignment stem 18 of the trajectory guide 10 is thus properly aligned (see Figure 1C), and the guide member 17 can be locked in place to allow for the insertion of a interventional device or other instrument.

Moreover, although it seems simplest to envision that the line bisect the trajectory guide alignment plane, in reality, what is needed is only that the point of intersection be predictable, such that the true point of intersection be determinable on the image of the trajectory guide alignment plane and the orientation of the trajectory guide alignment stem seen in cross-section to its longitudinal axis may be adjusted so as to bring the two points in alignment.

At this point, for purposes of verification, although not mandatory, one or more repeat scans are obtained through the intended target and through the length of the trajectory guide. Preferentially, in the case of MR imaging, scans of orthogonal (or approximately orthogonal) plane should be performed to ensure proper alignment. Alternatively, orthogonal (or approximately orthogonal) multiplanar reconstruction can then be performed on the operator console once again, which should clearly demonstrate the alignment stem 18 properly aligned along the intended trajectory to the target. Examples of such scans are shown in Figures 2A and 2B.

Once the trajectory guide is locked into position, the alignment stem 18 is removed from the trajectory guide and either the twist drill or, if a hole has already been made through the calvarium, the interventional device itself or other probe or instrument, depending on the circumstances of the procedure, can be passed to a predetermined depth by measuring off the confirmatory scans or the multiplanar reconstruction. Likewise, repeat scans can be obtained through the target itself which either will include the trajectory, if the patient's head was

tilted to the extent that the trajectory guide is within the plane, or only to show the target with the arrival of the tip at the target on one of the sequential scans.

The methodology described in the example above pertained to a lesion that was approached along the long axis of the patient. In fact, the same
5 methodology works equally well in other orientations to the long axis of the scanner. In other words, a temporal lobe biopsy is likely to be approached along an orientation perpendicular to the long axis of the patient. In the former case, what is referred to below as "the trajectory guide alignment plane" is oriented roughly perpendicular to the long axis of the patient. In the latter case, this plane
10 will be roughly aligned with the long axis of the patient, also commonly referred to as axial or transverse, or oblique axial or oblique transverse, typically sagittal or coronal with respect to the patient, or somewhere between these two orientations.

Moreover, although it seems simplest to envision that the line bisect the
15 trajectory guide alignment plane, in reality, what is needed is only that the point of intersection be predictable, such that the true point of intersection be determinable on the image of the trajectory guide alignment plane and the orientation of the trajectory guide alignment stem seen in cross-section to its longitudinal axis may be adjusted so as to bring the two points in alignment.

20 Example Method Using Computed Tomography

While the methodology described in the example above pertains to surgical procedures performed under MR imaging guidance, the methodology can be applied similarly to CT scanning guidance. In such a situation, it is preferable, although not mandatory, to utilize a spiral CT scanner, for the sake of
25 time and efficiency. In the example of a brain lesion to be approached somewhat along the long axis of the patient, a baseline spiral CT scan is obtained, typically, although not necessarily, following the injection of intravenous iodinated contrast media. The target is chosen from the axial images displayed on the scanner console and a surface entry point is selected on the scalp/skull. Once this
30 is accomplished, a multiplanar reconstruction of the spiral (or non spiral) data set is performed and the methodology described above for MR is followed. In this scenario, what is referred to below as "the trajectory guide localizing plane" is oriented roughly perpendicular to the long axis of the patient, and actually is

likely to be scanning not through the patient at all, but through the air, beyond the patient's head, but still through the trajectory guide stem 18. Once aligned, a repeat spiral (or non-spiral) data set, although not mandatory, can be obtained through the patient and trajectory guide stem 18, and (approximately) orthogonal
5 multiplanar reconstructed images along the length of the actual trajectory can be viewed, for purposes of confirmation.

In addition, the methodology can work equally well on CT for lesions accessed along trajectories oriented other than longitudinal to the patient. However, CT is a different methodology than MRI and the method proposed
10 herein is not optimal, when used in the true axial plane (perpendicular to the long axis of the patient). Nevertheless, a minor modification of the typical scanning methodology does permit this trajectory method to succeed even when used to access a lesion in the axial plane. To accomplish this, three different methods are described below.

15 First, the trajectory alignment stem 18 can be easily maneuvered within the plane of imaging. Certainly the target and device can both be visualized in this plane, and as long as the full length of the needle is visualized, one can be assured that a relatively accurate approach is likely.

Second, the target 12 can be chosen by scanning in the axial plane,
20 typically as a spiral acquisition over a volume of tissue, such that multiplanar reformatting can be performed. An entry point can then be chosen at some obliquity away from the original true axial plane, at which time the scan plane can then be angled, which is common to all CT scanners, such that the image plane will be at some reasonable angle away from the planned trajectory (for
25 example by way of illustration only, about 5 to 15 degrees from the true axial plane). In addition, the scanner can also be angled in the opposite direction to the angled scan plane, to obtain a trajectory guide alignment plane. Furthermore, once the trajectory guide is locked in place the patient may be moved forward or
30 backward on the gantry so that the trajectory guide alignment plane is positioned to view the target. Thus, the arrival of the interventional device at the target may be determined using the same image plane as used to position the guide. In this scenario, however, the mathematical calculations described below still prevail

and a predictable intersection of the trajectory and the trajectory guide alignment plane will be evident.

Finally, a third methodology provides that once the target and entry point are selected (in the axial plane), the gantry can be angled (again, for example by way of illustration only, about 5 to 15 degrees), such that the angle of the new scan plane is such that the trajectory line and the trajectory alignment plane will intersect.

In the first and third methods, the trajectory can be truly axial to the patient. In the second method, the trajectory itself is modified to an oblique axial approach. This is actually a typical scenario for a liver biopsy where the ribs are often in the line of approach for an axial trajectory.

Thus, as described above, the invention, in one example embodiment, provides the following method (wherein the steps are not necessarily performed in the following order), illustrated in Figure 3:

1. The area of interest in the body is imaged to locate the target and approach (40).
2. A trajectory guide is placed in position on, in or near the body. The trajectory guide pivoting around a fixed point which may or may not be proximate the surface of the body, but would typically be at the surface or outside the body (41).
3. The coordinates of the target and pivot points as well as the orientation of the imaging plane are determined (42).
4. The trajectory guide alignment stem is imaged in a plane having an orientation approximately normal to the direction of the guide, or such that the plane at least intersects with alignment stem when it is aligned with the desired line of approach. This is referred to below as the "trajectory guide alignment plane" (43).
5. The intersection point of a line defined by the two points with the trajectory guide alignment plane is determined (44).
6. The intersection point is displayed as an in-plane target point on the trajectory guide image (45).
7. The image of the guide stem, viewed substantially from a view looking "down" its axis, is aligned to the in-plane target point on the trajectory guide

image (essentially by moving the stem in "x" and "y" directions until aligned), preferably but not necessarily in "real time" (46).

It is noted that the trajectory guide alignment plane need not be strictly orthogonal to the line intersecting the target and pivot point. Rather, it is only
5 required that the line not lie entirely in the trajectory guide alignment plane, so that the stem of the guide intersects with the plane.

Example Embodiment of Imaging Software/Device

According to one embodiment of the invention, there is provided imaging software operative on an imaging device to enable the above-described method.
10 As shown as a block diagram in Figure 4, an imaging system 50 includes imaging apparatus 52, computer processing unit 54 including software 56, and a display 58. Imaging apparatus 52 may be an x-ray imaging, a magnetic resonance imaging (MRI) imaging unit, or an ultrasound imaging unit. Apparatus 52 supplies imaging data to computer processing unit 54, which
15 processes the imaging data under control of software 56 to produce images that are displayed on display 58, or output to a image printing system (not shown).

According to this embodiment of the invention, software 56 includes one or more software components 60 which provide a user interface and supporting computer processing instructions to guide an operator through the application of
20 the methods of the present invention. This user interface and supporting processing instructions preferably include, at a minimum, operator tools to identify the coordinates of the target and pivot point of the guide, and to determine the line passing through these points and the intersection of that line with the trajectory guide alignment plane to ascertain and mark on the display
25 the alignment point on the imaging plane. These tools in one example embodiment include the ability to paint or "drop" a cursor mark at the target and pivot point using a pointing device such as a mouse, to establish the coordinates for calculating line 30, which may be done automatically once the cursor marks are established. These cursor marks could be "dragged and dropped" to move
30 them around the display, if desired. Components 60 also preferably include tools for assisting the operator in specifying the location of the trajectory guide alignment plane, and once the alignment point has been identified, allow ready selection of a view of the imaging plane that allows alignment of the guide stem

with the marked alignment point. Further, it is contemplated that the operator, once having marked the target and the pivot point, can invoke the components 60 to automatically display, in several simultaneous windows on the scanner display, images such as those illustrated in images of Figures 1B, 2A and 2B, such that the stem 18 can be aligned with reference to the trajectory guide alignment plane image, and simultaneously the confirmatory images of Figures 2A and 2B (which can be alternatingly updated), which further allowing the stem 18 to be removed and the interventional device inserted to its desired location.

According to another aspect of the invention, there is provided an embodiment in which the positioning of the guide stem is accomplished automatically under control of the processing unit 54 and an electrical to mechanical linkage control 62, as illustrated in dotted-line form in Figure 4. In this embodiment, software components 60 include computer instructions to direct the electrical to mechanical linkage, through a suitable interface with the unit 54, to move the stem 18 until it aligns with the (x, y, z) coordinates of the alignment point, by comparing the position of the marker 19 to the desired alignment point. The mechanical linkage 64 may be of any design compatible with the imaging environment, such as disclosed in U.S. Patent Application Serial No. 09/078,913, identified more fully above.

Referring now to Figures 6 and 7, there are illustrated additional alternative embodiments of the invention, wherein alignment of the guide stem is facilitated. According to one embodiment, processing unit 54 outputs an audio signal that indicates if the stem is getting closer to or further away from alignment, or at least an indication when the stem is properly aligned. This indication may be, for example, a beep of variable frequency, with one end of the frequency range indicating the furthest away position, and the other end of the range indicating alignment. Determination of alignment of the stem may be accomplished by image analysis using unit 54. Alternatively, as illustrated in Figure 7, the stem may include a micro-coil 72 which may receive a signal from a signal source 74, or may be passive and configured to resonate at known frequency. The processing unit 54 can in turn be configured to detect a signal generated by the coil 72, and determine the spatial coordinates of the stem. Figure 6 also illustrates a laser light control unit 80 which receives an output

from unit 54 indicating the point in space the stem 18 is to be aligned with. Unit 80 controls a pair of lasers 82 and 84, which may be directed by mechanical linkage or otherwise so as to direct beams 83 and 85 to intersect at the point (e.g. 34) in space in which it is desired to align the stem 18. The stem 18 can then be readily aligned to the intersection of the beams, without reference to the image display. Of course, alignment could then be verified with respect to the image generated by the imaging apparatus. In another embodiment, other light sources could be used instead of laser light, such as infrared, or light of other frequencies or other energy sources focused at a point in space.

10 The invention further provides that the components 60 may be incorporated into the imaging system 50, or be distributed encoded in a carrier medium such as a magnetic media or digital data carried over an electrical or optical medium.

Theoretical Basis of Calculations

15 Set forth below is one example technique for finding a line or trajectory through two points in space graphically, as may be used in the present invention. For this example, assume that a target and pivot points are denoted respectively as

$$\begin{array}{c} \vec{r}_T \\ \vec{r}_P \end{array}$$

20 For the purposes of the invention, the coordinates of these two points are measured using the imaging system. The desired trajectory is defined by the line connecting these two points (T and P), and mathematically is defined as

$$\vec{r} - \vec{r}_P = k \hat{r}_{TP}$$

25 where r denotes a vector of any point along the line,

$$\hat{r}_{TP} = \frac{\vec{r}_{TP}}{|\vec{r}_{TP}|}$$

r_{TP} denotes a vector from the target point T to the pivot point P, and k is a parameter that measures the distance along the line from the target point "T".

In the frame of Cartesian coordinates, a plane can be generally defined as

$$\alpha x + \beta y + \gamma z = 1$$

where $\alpha\beta\gamma$ are three parameters for the normal of the plane, which satisfy the following relationship.

$$\sqrt{\alpha^2 + \beta^2 + \gamma^2} = 1$$

Alternatively, a plane through a point (r_0) can be defined as

$$\vec{r} - \vec{r}_0 = m_1 \hat{r}_1 + m_2 \hat{r}_2$$

where r denotes a vector of any point on the plane,

$$\hat{r}_i = \frac{\vec{r}_i}{|\vec{r}_i|}$$

($i=1,2$) are two unitary vectors parallel to the plane, and m_1 and m_2 are two real numbers. The two unitary vectors can be chosen to be orthogonal to each other for convenience. If they are orthogonal, then the inner product of the two unitary vectors is zero as shown below

$$\hat{r}_1 \cdot \hat{r}_2 = 0$$

And the normal vector of the plane is given by the cross product as shown below

$$\hat{n} = \hat{r}_1 \times \hat{r}_2$$

In general, a point on the plane can be expressed as follows

$$\vec{r} = \vec{r}_0 + m_1 \hat{r}_1 + m_2 \hat{r}_2$$

The equation above implies that each point on the plane corresponds uniquely to a pair of numbers (m_1 and m_2).

The intercept point between the line and the plane is given by the solution of the following vector equation.

$$\vec{r}_p + k\hat{r}_{rp} = \vec{r}_0 + m_1\hat{r}_1 + m_2\hat{r}_2$$

Solving this vector equation numerically, the corresponding m_1 and m_2 as
5 well as the parameter k for the point of interception can always be obtained.
This absolute interception point can be translated to a point on the scanned
image which has a limited field of view (FOV) and resolution, and can be
graphically displayed. When the image of the reference guide is adjusted to
coincide with the in-plane target point on the image, the reference guide is
10 guaranteed to be in the same direction defined by the two points (target and
pivot).

Thus, there has been described above method and apparatus for
positioning an interventional device in a body using a cross sectional imaging
system. Although the invention is described in one embodiment as a method of
15 obtaining a biopsy in the brain of a human, it is in no way limited to use in
obtaining biopsies or for human use. Also, although the invention was described
above with respect to a MRI scanner, it is applicable to any cross sectional
imaging/scanning system, such as a CT-scanner, PET scanner or ultrasound
scanner. The invention provides for a quick and precise way to obtain the proper
20 alignment of the guide, thereby improving the efficiency of use of the scanning
equipment and speeding the procedure and lessening the time of discomfort for a
patient. Although the invention has been described in a preferred form, it shall
be understood that many modifications and changes may be made thereto
without departing from the scope of the invention as defined in the claims
25 appended hereto.

In the claims:

1. A method of positioning a guide for an interventional device in a body, wherein the guide pivots about a pivot point, comprising locating the spatial
5 coordinates of a target and the pivot point, determining a third point outside of the body lying along or proximate a line extending through the target and pivot point, and aligning an axis of the guide with the third point in an image taken in an alignment plane containing or substantially containing the third point, wherein the line does not lie in the alignment plane.
10
2. A method according to claim 1 wherein the alignment plane is orthogonal or substantially orthogonal to the axis of the guide.
3. A method according to claim 1 wherein the angle between the alignment
15 plane and the line is at least great enough to allow a MR visible component located proximate the axis of the guide to be viewed in an image taken in the alignment plane and so as to permit the MR visible component to be used to align the axis with the third point in the image of the alignment plane.
- 20 4. A method according to claim 3 further wherein the third point is marked on the image and the axis of the guide is located by imaging at least a portion of an alignment stem of the guide.
- 25 5. A medical imaging system including a processing unit and computer software operative in the processing unit to permit an operator of the system to locate the spatial coordinates of a target point and a pivot point of a guide for an interventional device to be located in a body, and automatically determine a third
30 point outside of the body lying along or proximate a line extending through the target and pivot point, wherein the third point is located at a distance from the body allowing an image plane to be obtained in a space outside the body and wherein the image plane contains or substantially contains the third point.

6. A medical imaging system according to claim 5 wherein the computer software is further operative on the processing unit to display an image taken on a guide alignment plane within or substantially within which the third point lies and which intersects with an alignment axis of the guide, and further operative to
- 5 display a mark on the image which indicates the position of the third point to allow the alignment axis of the guide to be aligned with the third point in the plane of the image.
7. A medical imaging system according to claim 6 further wherein the
- 10 computer software is further operative on the processing unit to assist an operator in obtaining an image by which the axis of the guide can be aligned with the third point.
8. A medical imaging system according to claim 7 wherein the computer
- 15 software is further operative on the processing unit to allow the target and pivot point to be marked using a pointing device and to automatically calculate the line extending through the target point and the pivot point, and to further determine and display the image taken along the guide alignment plane.
- 20 9. An article of manufacture comprising a computer program encoded in a carrier, wherein the program is operative on a processing unit of a medical imaging system to permit an operator of the system to locate the spatial coordinates of a target point and a pivot point of an interventional device to be located in a body, and automatically determine a third point outside of the body
- 25 lying along or proximate a line extending through the target and pivot point, wherein the third point is located at a distance from the body allowing an image plane to be obtained in a space outside the body and wherein the image plane contains or substantially contains the third point.
- 30 10. An article of manufacture according to claim 9 further including a computer program operative on the processing unit to assist an operator in obtaining an image by which the axis of the guide can be aligned with the third point using an imaging system.

11. A method of positioning a guide for an interventional device in a body, wherein the guide pivots about a pivot point, comprising locating the spatial coordinates of a target and the pivot point, determining a third point outside of the body lying along or proximate a line extending through the target and pivot point, and aligning an axis of the guide with the third point by obtaining an image in an alignment plane wherein the third point is in the plane and the axis intersects the plane so as to permit the point of intersection of the axis and the third point to be aligned with one another in the image.
12. A method according to claim 11 wherein the interventional device is a biopsy needle or a drug delivery probe.
13. A method according to claim 11 wherein the line extending through the target and pivot point is substantially parallel to a long axis of a patient.
14. A method according to claim 11 wherein the line extending through the target and pivot point is substantially orthogonal to the long axis of the patient.
15. A method according to claim 11 wherein the images are determined using a computed tomographic (CT) scanner, a magnetic resonance imaging (MRI) device, or an ultrasound imaging device.
16. A method of positioning a guide for an interventional device in a body, wherein the guide pivots about a pivot point, comprising locating the spatial coordinates of a target and the pivot point; determining at least a third and fourth points outside of the body lying along or proximate a line extending through the target and pivot point, and aligning an axis of the guide initially with the at least third point in an image taken in an alignment plane containing or substantially containing the at least third point, wherein the line does not lie in the alignment plane, and subsequently with the fourth point outside of the body lying along or proximate a line extending through the target and pivot point, and aligning an axis of the guide with the third and fourth points and the target point, in such a

manner that may correct for slight imprecision at the pivot point, such that an even more accurate trajectory can be achieved along the line connecting the target point, the pivot point and the at least third and fourth points.

- 5 17. A method of positioning a guide for an interventional device in a body comprising using imaging apparatus to locate a position outside of the body and using the position to align the interventional device.
- 10 18. A method according to claim 17 wherein the interventional device is aligned with the position with the aid of an audible or visible signal.
19. A method according to claim 18 wherein an audible property of the audible signal changes to aid in positioning the device.
- 15 20. A method according to claim 18 wherein the visible signal is provided by a laser light.
- 20 21. Apparatus for positioning a guide for an interventional device in a body comprising imaging apparatus adapted to locate a position outside of the body that provides for alignment of the interventional device.
22. A method according to claim 21 wherein the interventional device is aligned with the position with the aid of an audible or visible signal.
- 25 23. A method according to claim 22 wherein an audible property of the audible signal changes to aid in positioning the device.
24. A method according to claim 23 wherein the visible signal is provided by a laser light.

FIG. 1A

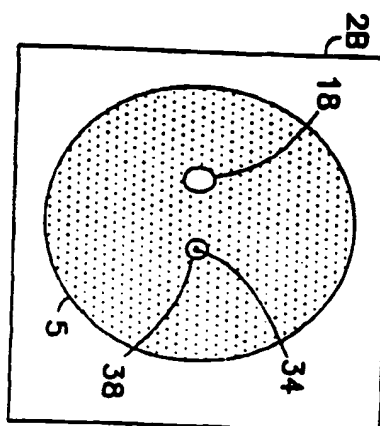


FIG. 1B

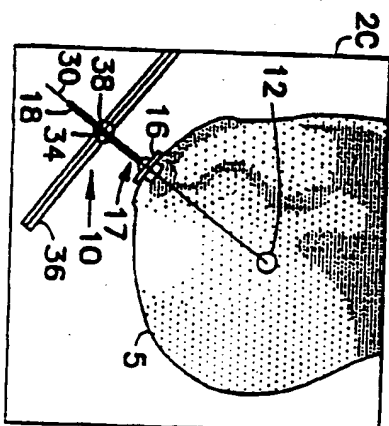


FIG. 1C

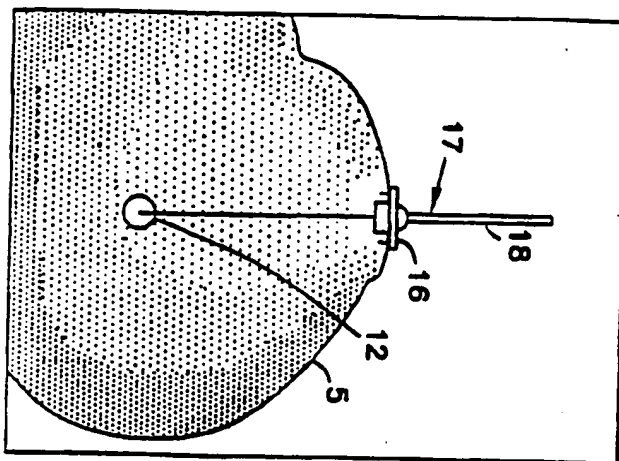


FIG. 2A

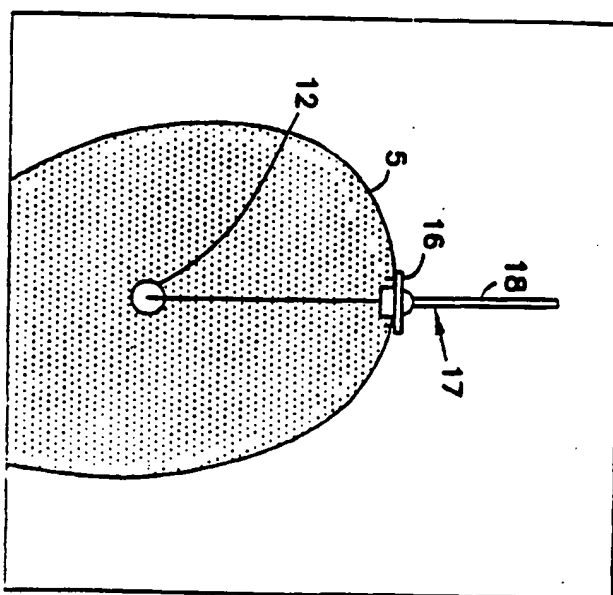


FIG. 2B

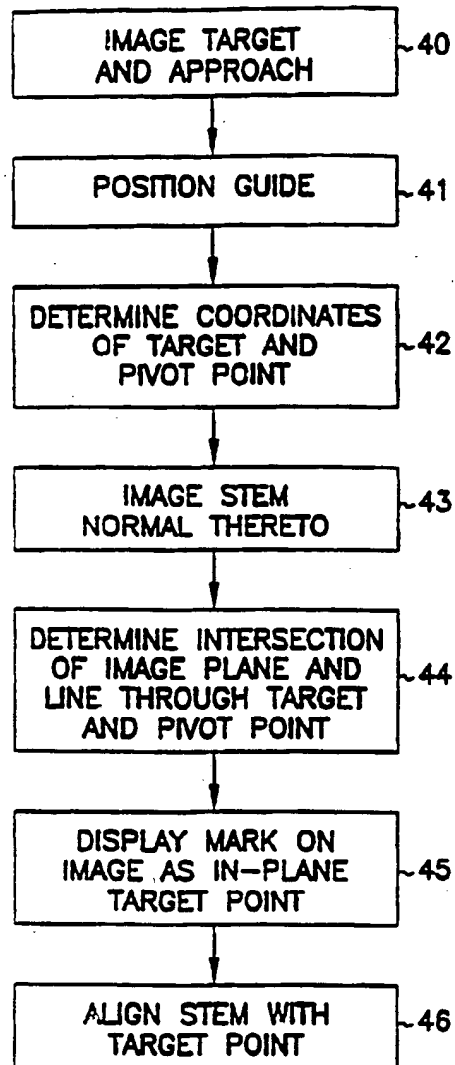


FIG. 3

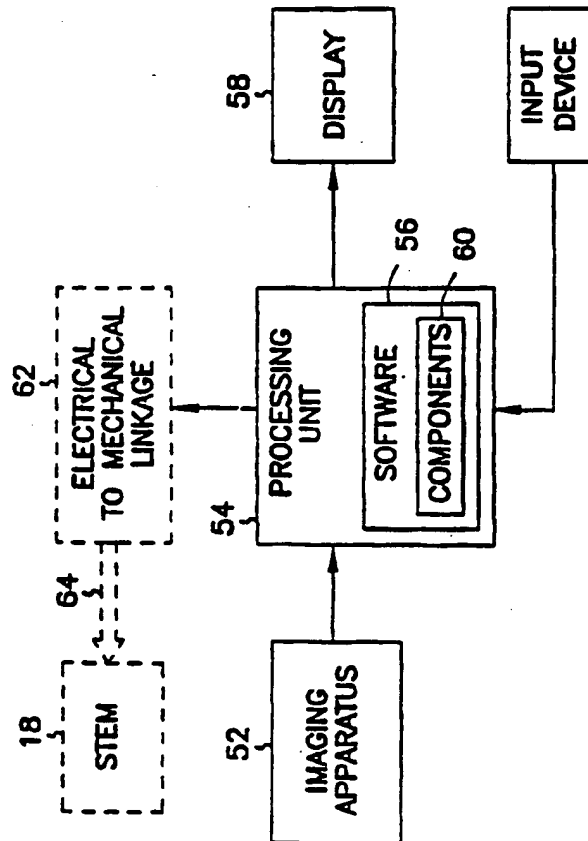
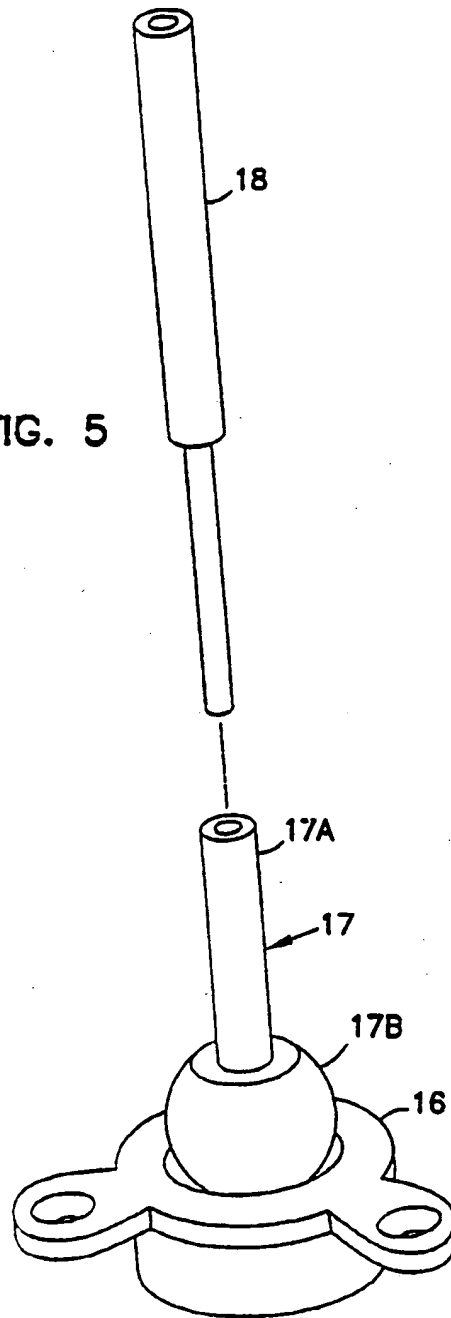


FIG. 5



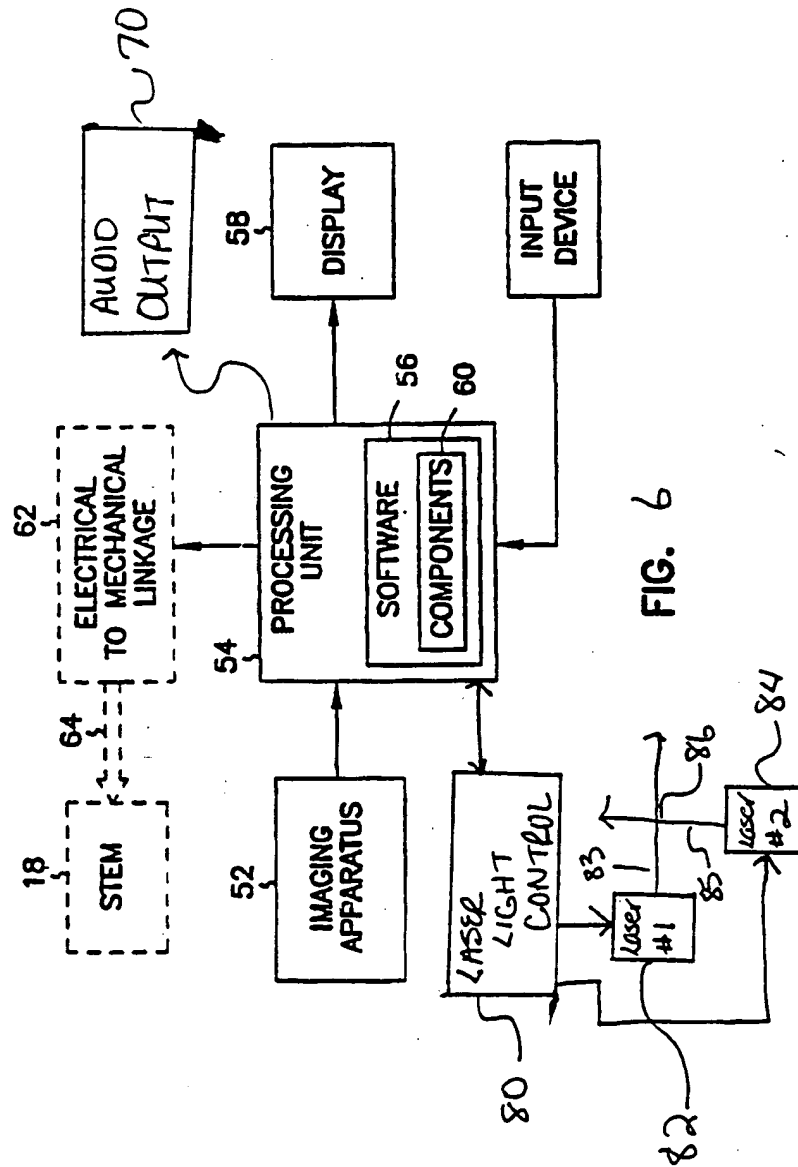
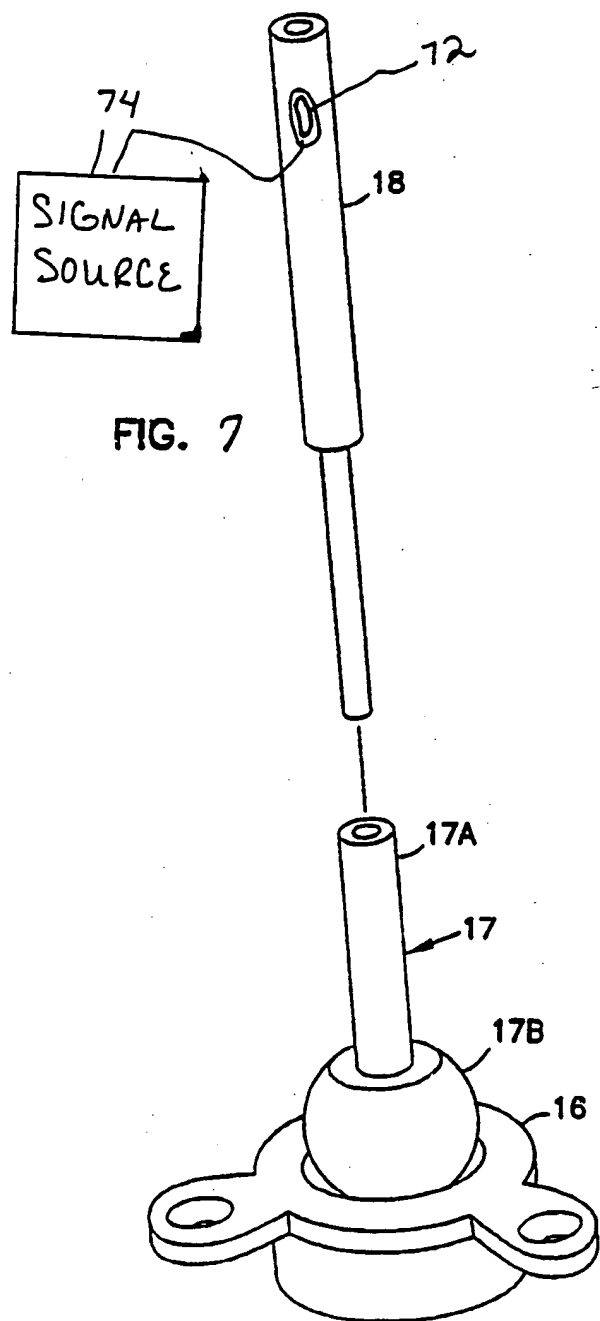


FIG. 6



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/23673

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP 0 832 611 A (ALLEN GEORGE S) 1 April 1998 (1998-04-01) column 5, line 8 - line 51; figure 4 ---	1,3-15, 17,21 2,16
X Y	US 5 810 841 A (LANDI MICHAEL K ET AL) 22 September 1998 (1998-09-22) column 6, line 20 - line 32 ---	17,18, 20-22,24 19,23
X	US 5 782 842 A (FRAHM CHRISTIAN ET AL) 21 July 1998 (1998-07-21) column 3, line 29 - line 37 column 3, line 55 - line 61; figure 1 ---	17,18, 20-22,24
X A	US 5 776 143 A (ADAMS LAURENCE PENTECOST) 7 July 1998 (1998-07-07) column 3, line 7 - line 45; figure 6 ---	17,21 1,5,9, 11,16
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

19 January 2000

Date of mailing of the international search report

26/01/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Mayer, E

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/23673

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
Y	EP 0 486 269 A (ADVANCED TECH LAB) 20 May 1992 (1992-05-20) column 7, line 43 - line 52 -----	19, 23

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte. onal Application No

PCT/US 99/23673

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0832611	A	01-04-1998	US : 5984930 A	16-11-1999
			JP 10174687 A	30-06-1998
US 5810841	A	22-09-1998	AU 4898397 A	11-12-1998
			NO 993569 A	16-09-1999
			WO 9852485 A	26-11-1998
			HR 980020 A	31-08-1999
US 5782842	A	21-07-1998	DE 19501069 A	18-07-1996
US 5776143	A	07-07-1998	AU 693852 B	09-07-1998
			AU 1671995 A	04-09-1995
			EP 0744925 A	04-12-1996
			WO 9522297 A	24-08-1995
			ZA 9502438 A	25-09-1996
EP 0486269	A	20-05-1992	US 5158088 A	27-10-1992
			AT 136755 T	15-05-1996
			AU 6916791 A	18-07-1991
			DE 69118823 D	23-05-1996
			DE 69118823 T	05-09-1996
			EP 0506733 A	07-10-1992
			WO 9108706 A	27-06-1991
			JP 6043242 A	18-02-1994
			JP 5502392 T	28-04-1993

THIS PAGE BLANK (USPTO)